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April 27, 2020

Michael L. Goodis, P.E.
Director, Registration Division (RD)
Office of Pesticide Programs (OPP)
Mail Code 7505P
USEPA Headquarters, William Jefferson Clinton Building
1200 Pennsylvania Avenue, N. W.
Washington, DC 20460

RE: BASF Corporation's Response to US EPA's April 27, 2020 Letter to Max Safarpour
"Information Concerning Dicamba That Must Be Reported Pursuant to FIFRA §6(a)(2)"

Dear Director Goodis:

BASF Corporation (BASF) is writing in response to the referenced letter to Max Safarpour, BASF, in which EPA reminded BASF of its reporting obligations under FIFRA §6(a)(2), 40 CFR §159, and EPA's 2018 amendments to the Engenia® Herbicide registration requiring enhanced reporting of certain adverse effects information. (EPA Reg. No. 7969-345; Decision No. 544935 dated 11/2/18). While BASF has full confidence in the sufficiency of the §6(a)(2) information it has submitted to-date on dicamba, and might ordinarily question whether each of the information sub-categories set forth in EPA's Letter necessarily qualify as §6(a)(2)-reportable information, we have chosen to set aside such reservations in the interest of ensuring that EPA has a robust record from which to make its re-registration decision.

We appreciate having the chance to discuss the scope of EPA's Letter during our April 8, 2020 conference call. As BASF confirmed with EPA the following day, we enclose or have otherwise arranged to transmit to EPA the following information in response to EPA's Letter:

I. **Supplemental 6a2 Incident Information:**

In Section I of BASF's response, which is provided via separate letter dated April 27, 2020 from John J "Jack" Arthur to Margaret Hathaway, Senior Regulatory Specialist, Registration Division, BASF has supplemented its 2017-2020 6a2 incident spreadsheets (previously submitted to EPA) with additional information in its possession describing incident location and proximity information, including the town's identity, empirical data/quantitative information describing the scope of the off-target impact, distance from the impact to the site of application, and related weather information (wind speed, direction, etc.).

BASF Delivery to EPA: As stated above.

II. **Dicamba-Contaminated Trials/Study Plots:**

In this Section II, BASF describes any BASF, university or other cooperator studies/trials during 2017-2020 that were interrupted or terminated because of dicamba contamination in the studied field or greenhouse, or contamination of experimental controls.

Should EPA find that a university or cooperator declines to share information with EPA on such interrupted or terminated BASF trials, claiming that its research agreement with BASF restricts it from disclosing such data to third parties, BASF agrees to take reasonable action to waive such restriction. If EPA is aware of any universities with such data, who believe they cannot share it with EPA due to a BASF contractual restriction, BASF requests that EPA inform us of the details so we can work to facilitate release of the study information.

BASF Delivery to EPA: Detailed information provided below:

Field Biology Research and Development Studies:

The BASF Biology field group is not aware of any BASF internal or sponsored external trials that were compromised due to off-target-movement of dicamba. BASF conducted 4458 internal and external trials across indications (Fungicide, Herbicide and Insecticide) and crops (e.g. row, field, specialty, turf and ornamental) between 2017 and 2019. Approximately half of the trials (mostly Fungicide and Insecticide) were conducted by external cooperators. There were a few anecdotal comments about occasional light soybean epinasty or leaf cupping (<5% visual injury) that could have been caused by herbicide off target movement, but there was no confirmation of the source or substance identification and the impact to the test plants never resulted in a negative impacted on the trial results.

Regulatory Field and Greenhouse Studies:

A few Regulatory studies have been negatively impacted by dicamba off target movement between 2017 and 2019:

- One large scale dicamba off target movement field study in Missouri, that was part of the 2018 required additional data requirements, was exposed to an external source of dicamba at the time of study initiation. This was not known at the time of study initiation, but active air sampling conducted according to the study protocol prior to the planned dicamba application in the study detected dicamba residues in the air samples collected. This was only discovered after the analysis of the active air sample filters, after the field portion of the study had been completed. The external source of the detected dicamba in the air samples was not identifiable.

  During the conduct of the field portion of the study, a uniform low level of soybean injury (<15%) was observed in much of the study site and surrounding untreated soybeans. The study was completed, but exposure of the study site to an external source of dicamba confounded the injury observed in the study that could not be directly attributable to the applied dicamba within the study. This information is fully disclosed within the submitted study report (MRID 51049002) on page 17.

- A second large scale dicamba off target movement field study in Mississippi, that was part of the 2018 required additional data requirements, was exposed to an external and possible movement of intentionally applied dicamba with the study, by flood waters that partially inundated the study site and surrounding field within 36 hours after the intended dicamba application was made. Soybean injury that was observed and measured subsequent to the flooding event suggest that the flood waters contained dicamba residues. Later analysis of a grab sample of the flood water from the study site measured a significant dicamba residue concentration in the flood water sample.

The information is fully disclosed within the submitted study report (MRID 51049003) on pages 3,14,15,18,118,541-543,634,639-660,713,715 and 744.

- On three occasion during the conduct of required Vegetative Vigor studies with dicamba products the greenhouse testing facility had problems with dicamba cross contamination between the study plants, resulting in dicamba soybean injury symptomology in the untreated soybean control plants. Once this was discovered, usually during the 14-day observation interval, that portion of the study was terminated, and the soybeans were replanted to be treated again at the appropriate growth stage. The overall impact was a delay in completing the full study. There was no negative impact on the study since one of the validation checks for the study is to confirm that the plants did not exhibit visible phytotoxic effects (e.g., chlorosis, necrosis, wilting, leaf and stem deformations). Once these symptoms were observed in the untreated control soybeans the soybean portion of the study was terminated and reinitiated.

III. **Documents from Off-Target Drift Claim Litigation:**

In Section III of the attached response, BASF has separately arranged for transfer to EPA of copies of the following electronic files:

1. The Protective Order in the Dicamba Multi-District Litigation ("MDL")[1] (including Bader Farms[2]);
2. Documentary evidence introduced by BASF at Bader Farms trial;
3. Documentary evidence introduced by Plaintiff at trial that was produced by BASF or third parties (excluding documents produced by Monsanto);
4. Expert reports on liability from BASF and Plaintiffs (MDL and Bader Farms):
    a. Deposition Transcripts of Plaintiffs' liability experts;
    b. Briefs on Daubert Motions addressing Plaintiffs' liability experts;
    c. Court Rulings on Daubert Motions; and
5. The Bader Farms Trial transcript

BASF Delivery to EPA: File Transfer Protocol link emailed to Margaret Hathaway, US EPA on or about April 27, 2020 from or on behalf of John Mandler, Attorney for BASF Corporation.

A. Dicamba MDL

BASF notes that the Dicamba MDL is ongoing. While Plaintiffs have submitted expert reports addressing the merits of their claims, BASF (and Monsanto) submitted counter expert reports on the same issues. Moreover, after the Plaintiff experts were deposed, Defendants moved to exclude the opinions of Plaintiffs liability' experts (Dr. Stevan Knezevic, Dr. Dennis Gardisser and Dr. Ford Baldwin) under *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 597 (1993), because the experts failed to follow a scientifically valid methodology. The Court granted Defendants motion in part, *In re Dicamba Herbicides Litig.*, MDL No. 2820, Memorandum and Order (E.D. Mo. Nov. 27, 2019), excluding the opinions of Plaintiffs' experts as follows:

[1] In Re Dicamba Herbicides Litigation, Case No. 1:18-md-02820-SNJL (E.D. MO).
[2] Bader Farms, Inc. v. Monsanto Co., et al., Case No. 1:16-cv-00299-SNLJ (E.D. MO).

1. **Dr. Stevan Knezevic**

- "Dr. Steven Knezevic, Ph.D., is a weed scientist at the University of Nebraska . . . He was retained to provide opinions regarding the dose response of soybeans exposed to dicamba, including Xtendimax and Engenia."

- "[P]laintiffs admit that Knezevic is not offering an opinion on the Xtendimax and Engenia volatilization rates." (7)

- "Knezevic admits that plants absorb liquid differently from gas—plants take in gas through stomates, on the bottom of the leaf, whereas liquid can be absorbed anywhere the plant has green tissue." (7-8)

- "[I]t is undisputed that the concentration of dicamba in gaseous form is typically lower than the concentration of dicamba in liquid form. . . . Knezevic admitted that he 'has not done any' research and 'is not aware of any data' on this issue, so he "cannot say" whether vaporized dicamba would affect soybeans the same as liquid." (8)

- "According to Monsanto's statistics expert Dr. George Milliken, Knezevic should have conducted 150 replications in order to detect a 1% yield loss with statistical reliability. This, Milliken says, is the minimally accepted standard for statistical reliability set by the EPA and USDA, which require levels of 95% confidence at a power of 80% (still allowing a 20% chance that random fluctuations could have generated the results). Plaintiffs acknowledge that such data would be required for "hypothesis testing," but that Knezevic was instead "estimating [the] size of effects." . . . Milliken testified that that the EPA and USDA require that experiments have an 80% power of detecting a certain specified difference between two treatments. Regardless of how Knezevic characterized his study, he was studying the difference between a zero dose of dicamba and a dose that would result in a 1% to 5% reduction in yield. The EPA and USDA's standards would require 150 replications of such a study, not four. Tellingly, however, plaintiffs do not identify what other standard is appropriately applied to ensure the statistical significance of Knezevic's study." (9)

- "The limitations of Knezevic's data set is underscored by another problem: yield variability. For Knezevic's 12 controls—those with no dicamba exposure—yields ranged from 3,656 kg/ha to 4,763 kg/ha with an average of 4,461 kg/ha.3 But Knezevic's range of yields for a dicamba exposure of 1/1000 of the labeled rate at the full flowering stage is 3,797 to 5,064 kg/ha, a yield range within or above the range of the unexposed controls. . . . there is no statistical significance where Knezevic's own model suggests that the same yield is expected regardless of whether soybeans are exposed to dicamba. Plaintiffs reply that the variability is expected when measuring biological parameters. But this is not helpful where the dicamba-exposed soybeans produced anywhere from a 13.5% yield gain to a 14.9% yield loss when compared to the average unexposed control. This Court is confounded by these results and the plaintiffs' failure to explain them." (10)

- "In sum, the Court will exclude Knezevic's opinions as to the volatility rate of Xtendimax and Engenia, Knezevic's dose-response opinions, and his opinions on the effect of multiple exposures." (14)

2. **Dr. Dennis Gardisser**

- "Dr. Dennis Gardisser is an agricultural applications expert . . . retained . . . to explain off-target movement of dicamba." (14)

- "Gardisser relied on the defendants' own test results, which were submitted to the EPA and which the EPA summarized in a report . . . however, Gardisser admitted in his deposition that the EPA's modeling showed that the amount of volatilized dicamba reaching the edges of dicamba-treated fields did not reach or exceed the "no-effect level" for dicamba on soybeans. In addition, Gardisser opines that he relied on Knezevic's numbers for the dicamba dose that would cause yield loss, and this Court has excluded Knezevic's opinion on that matter." (15)

- "Gardisser extrapolates his opinions to the myriad fields in other states that he did not visit. . . . Gardisser admitted some fields he visited showed symptoms of exposure from dicamba drift rather than inversions. . . . In fact, Gardisser stated that 14% of the symptoms he observed were caused by off-label misapplication of dicamba resulting in drift, tank contamination, or some other unknown source. Fields that are exposed to dicamba spray carried by wind (*i.e.*, drift) show more symptoms closer to where the spraying occurred and fewer symptoms as one moves away from it." (16-17)

- "Ultimately, Gardisser cannot opine that volatilized dicamba caused "uniform, class-wide damage" to plaintiffs' non-DT soybeans while also admitting that some 14% of fields showed evidence of another contamination vehicle, like drift, which by definition causes non-uniform damage. The Court finds that his opinion is neither reliable nor helpful . . . This opinion will be excluded." (17)

3. **Dr. Ford Baldwin**

- "Dr. Ford Baldwin is another weed scientist who . . . opines that every non-DT soybean field in the eight states at issue was exposed to dicamba through off-target movement of dicamba applied to Xtend seeds because of dicamba's volatility and long-range transport." (18)

- "Baldwin opines that non-DT soybeans across eight states experienced uniform dicamba symptomology that resulted in damages. However, Baldwin has never even visited soybean fields in Nebraska or South Dakota, and he made no substantial observations in Mississippi, Tennessee, and Illinois. He personally observed fields only in Arkansas and southeast Missouri." (19)

- "But the leap Baldwin makes—extrapolating to non-DT soybeans in eight states from his observations in Missouri and Arkansas—goes too far. Baldwin's own articles discuss, on a case-by-case basis, the multiple factors that may impact and contribute to off-site movement of an herbicide. For example, he has identified "drift from an adjacent field, drift from long distances,

temperature inversion issues, plane getting in the wrong field, farmer getting his own fields mixed up, contamination in the load [and applicator] mess-ups [and] unlabeled containers," as well as tank contamination. Baldwin also admits that crops can recover from herbicide injury, and he typically returns to fields to see if symptomology changes. Baldwin's opinions here do not allow for those considerations and mitigating conditions." (19-20)

- "The Court concludes that, although Baldwin clearly has the qualifications and experience to opine on the volatility and off-target movement of dicamba, his opinions related to dicamba injuries to fields he has not visited must be excluded." (20)

B. Bader Farms v. Monsanto.

The *Bader Farms* case is the only case within the MDL to be tried to a jury. In *Bader Farms*, Plaintiffs claimed that dicamba products that were illegally applied over the top of DT cotton and soybean seed in 2015 and 2016 moved off target to Bader Farms' peach fields causing injury. Plaintiffs' expert Dr. Ford Baldwin admitted that he could not opine on the source or the identity of the illegally applied dicamba product(s). Plaintiffs claim that injury from off-target movement of dicamba continued in 2017 and subsequent years. For those years, Dr. Baldwin admitted that he also could not identify the source or the specific dicamba product(s) at issue. Monsanto and BASF's experts opined that there was no evidence of dicamba injury to the Bader Farms peach trees and further documented the presence of a significant amount of armillaria root rot (*Armillaria tabescens*) causing yield loss and tree death. The jury nonetheless found Monsanto and BASF liable for the alleged yield loss.

The Bader Farms matter is ongoing. Currently post-trial motions are pending, and Monsanto and BASF will appeal the case to the Eighth Circuit Court of Appeals.

In closing: Both in its April 27th letter and during our April 8th meeting, EPA expressed the need to have the requested information provided as soon as possible. BASF supports and encourages this sense of urgency. We believe it is in the agricultural community's best interest that EPA have the information needed to facilitate making a timely decision on the re-registration of dicamba for over the top applications, including Engenia® Herbicide (EPA Reg. No. 7969-345), as well as registering new formulations. BASF respectfully requests that EPA make its re-registration decision by August/September so farmers can make Dicamba-tolerant (DT) seed purchasing decisions, and so BASF may pursue any necessary label amendments describing new use directions and provide timely applicator training.

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Please contact me by email at john.arthur@basf.com or mobile phone at (973) 960-7897 should you have any questions or concerns.

Respectfully submitted,

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